



UNITED STATES  
PATENT AND  
TRADEMARK OFFICE

DEC - 6 2001

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND  
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
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In re Application of :  
McCafferty et al :  
Serial No.: 09/196,673 : PETITION DECISION  
Filed: November 20, 1998 :  
Attorney Docket No.: 13839-00003 :

This is in response to applicants' petition filed under 37 CFR 1.181 and 1.183 on 11 October 2001, to request that a sequence listing not be required for the present application.

The petition was filed in response to an Office action mailed by the examiner dated 24 September 2001, which stated that the application failed to comply with the Sequence Listing requirements of 37 CFR 1.821-1.825. Specially, applicants failed to provide a computer readable form of the sequence listing and a paper copy of the sequence listing along with a statement that the contents of the paper copy and computer readable form are the same and that no new matter has been added.

A review of the '673 file shows that the instant application was filed as a continuing application under 35 U.S.C. 111 (Paper No. 2 filed 11/20/98) which claims priority to US SN 07/971,857, filed 8 January 1993, under 35 U.S.C. 371 as national stage filing of PCT/GB91/01134, filed 10 July 1991. The exemption from filing a sequence listing as discussed in MPEP 2421 is limited to the national stage filing under 37 C.F.R. 371. In the instant application's lineage, that exemption is only granted to the 07/971,857 application which was the national stage filing under 35 U.S.C. 371 and was filed prior to implementation of equivalent PCT Administrative Instructions (see Annex C).

Continuations and divisionals of national stage applications are filed under 35 USC 111 and are treated as new applications. As such, this new application is required to comply with 37 C.F.R. 1.821-1.825.

The Petition asserts that compliance with the requirements of 37 C.F.R. 1.821-1.825 may be waived under exceptional circumstances and cites MPEP 2421.01. Applicants submit that requiring the present application to comply with the Sequence Listing Rules would place undue hardship on applicants because the sequence data is currently not available on any computer readable form. Applicants further submit that manually entering the formatting the numerous peptide and nucleotide sequences would require a huge expenditure of time and expense without providing commensurate benefit to either the USPTO or the public, especially in view of the fact that none of the sequences are being claimed. Finally, the petition asserts that submitting a second substitute specification would be excessively time consuming.

These arguments have been considered carefully and found to be not persuasive for the following reasons.

(1) With regard to the burden of filing a substitute specification, it is noted that compliance with the sequence requirements does not necessarily result in need for a substitute specification.

A review of the 299-page specification shows that sequences are found on pages 118 and 120, for example. Applicants may insert the SEQ ID Nos. for these sequences by replacing the text of the paragraph within which the sequence is found. Additionally, a sequence listing can be added, by amendment to the specification.

A review of the 53 drawings shows that sequences are present in Figures 5 and 52, for example. In order to comply with the sequence requirements, SEQ ID Nos. need to be added to the specification to describe those sequences recited in the Figures. This may be accomplished by filing new drawings that recite the SEQ ID Nos. Alternatively, the SEQ ID Nos. may be added as amendments to the Brief Description of the Drawings to describe the sequences in the Figures. These amendments would be similar to those which applicants have already filed as Amendment E, filed 23 June 2001 as Paper No. 16, in which portions of the Brief Description of the Drawings were amended.

As no sequences are recited in the 100-plus claims, no amendments to the claims are required for compliance to the sequence requirement.

While it is acknowledged that compliance with the sequence requirements will require a lengthy amendment, the amendment is not likely to be as extensive as the amendments already on file in this application, notable the 20 page amendment filed 23 July 2001 as Amendment E, or the 17 page amendment filed 10 October 2000 as Paper No. 11 or the 18 page Preliminary amendment filed 20 November 1998. It is difficult to argue that undue hardship would be incurred by compliance with the sequence requirements, as lengthy amendments appear to be the norm rather than an exception for this application.

(2) With regard to the difficulty of manually entering and formatting the disclosed peptide and nucleotide sequences to a computer readable form, applicants should note that the conveyance of written material to an electronic format is becoming more and more standard. Electronic scanning devices may aid applicants in their effort to convert the written sequences to a computer readable format. Further, assistance in downloading the PatentIn 3.1 software can be obtained from General Information Service at (800) 786-9199 or (703) 308-4357. Additional help related to using the PatentIn 3.1 software can be obtained by calling the PatentIn Help Line at (703) 306-4199 or by e-mail at [patin3help@uspto.gov](mailto:patin3help@uspto.gov).

(3) With regard to the commensurate benefit, applicants' compliance with the sequence requirements will enable examiners to easily identify this pending application as prior art when searching other applications claiming the disclosed sequences. This benefit will be extended to the public should the application go on to issue and should the sequences be contained in the USPTO's issued sequence database. Although sequences are not currently recited in the claims, during prosecution, applicants may wish or need to include particular peptide or nucleotide sequences in the claims. Once the case goes on to issue, surely applicants benefit by the inclusion of any disclosed or claimed sequences in the USPTO's pending and issued databases so that interfering subject matter and prior art can be easily identified. Also, a U.S. Patent is a right conveyed to applicants in exchange to disclosure of the invention. Part of applicants' disclosure is the sequences recited in the Figures and in the specification. Regardless of whether these sequences are recited in the claims, once the application goes on to issue, the contents of the disclosure need to be made available to the public in a format amenable to searching. It has been and remains standard practice that peptide and nucleotide sequences are searched using computer readable format.

For all of these reasons compliance with the sequence requirements will not be waived for this application.

Finally, applicants may choose to delete from the specification and drawings any sequences that are not (1) recited in the claims, and (2) required for enablement, written description, new matter or priority considerations.

Related application 08/273,146, filed 14 July 1994, and issued as U.S. Patent No 5,855,885 on 5 January 1999, also claims priority to PCT/GB91/01134 and has complied with the sequence requirements. If sequences are identical between these applications, the computer readable form may be easily transferred from '146 to the '673 application using the procedures set forth in MPEP 2422.05.

Applicants are required to comply with the requirements of 37 C.F.R. 1.1821-1.825, as set forth on the letter sent 24 September as Paper No. 17.

Therefore the petition is DENIED.

Applicants remain under obligation to reply to the Office Action of 24 September 2001, within the time period set or as may be extended under 37 CFR 1.136(a).

Should there be any questions with regard to this decision, please contact Julie E. Burke, Ph.D. by letter addressed to the Group Director, Technology Center 1600, Washington, DC 20231, or by telephone at (703) 308-7553 or by facsimile transmission at (703) 305-7939.

A handwritten signature in black ink, appearing to read "John Doll". The signature is fluid and cursive, with the first name "John" being more prominent than the last name "Doll".

John Doll  
Group Director  
Technology Center 1600